

#### General

#### Guideline Title

The official positions of the International Society for Clinical Densitometry: indications of use and reporting of DXA for body composition.

#### Bibliographic Source(s)

Kendler DL, Borges JL, Fielding RA, Itabashi A, Krueger D, Mulligan K, Camargos BM, Sabowitz B, Wu CH, Yu EW, Shepherd J. The official positions of the International Society for Clinical Densitometry: indications of use and reporting of DXA for body composition. J Clin Densitom 2013 Oct-Dec;16(4):496-507. [137 references] PubMed

#### Guideline Status

This is the current release of the guideline.

## Recommendations

## Major Recommendations

The definitions for quality of evidence (Good, Fair, Poor), strength of recommendations (A–C), and application of recommendations (W, L) are provided at the end of the "Major Recommendations" field.

What Are the Clinical Indications of Using Dual-Energy X-ray Absorptiometry (DXA) for Patients with Human Immunodeficiency Virus (HIV)?

International Society for Clinical Densitometry (ISCD) Official Position

DXA total body composition with regional analysis can be used in the following conditions: in patients living with HIV to assess fat
distribution in those using antiretroviral agents associated with a risk of lipoatrophy (currently stavudine and zidovudine). Grade: Good-B-W

What Are the Clinical Indications of Using DXA for Patients Either Considering or Having Recently Had Bariatric Surgery?

#### ISCD Official Position

 DXA total body composition with regional analysis can be used in the following conditions: in obese patients undergoing bariatric surgery (or medical, diet, or weight loss regimens with anticipated large weight loss) to assess fat and lean mass changes when weight loss exceeds approximately 10%. The impact on clinical outcomes is uncertain. Grade: Poor-C-W

What Are the Clinical Indications of Using DXA for Patients with Sarcopenia?

ISCD Official Position

• DXA total body composition with regional analysis can be used in the following conditions: in patients with muscle weakness or poor physical functioning to assess fat and lean mass. The impact on clinical outcomes is uncertain. Grade: Fair-C-W

What Are the Clinical Indications for DXA Body Composition in Obese Patients?

ISCD Official Position

• No position could be agreed on at this time.

What Are the Contraindications of DXA for Body Composition?

ISCD Official Position

Pregnancy is a contraindication to DXA body composition. Limitations in the use of clinical DXA for total body composition or bone
mineral density are weight over the table limit, recent administration of contrast material, and/or artifact. Radiopharmaceutical agents may
interfere with accuracy of results using systems from some DXA manufacturers. Grade: Fair-B-W

#### Definitions:

Quality of Evidence

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations.

Fair: Evidence is sufficient to determine effects on outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies.

Poor: Evidence is insufficient to assess the effects on outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Strength of Recommendations

A: Strong recommendation supported by the evidence

B: Recommendation supported by the evidence

C: Recommendation supported primarily by expert opinion

Application of Recommendations

W: Worldwide recommendation

L: Application of recommendation may vary according to local requirements

## Clinical Algorithm(s)

None provided

## Scope

## Disease/Condition(s)

- Sarcopenia
- Obesity
- Human immunodeficiency virus (HIV)-related lipodystrophy and lipoatrophy

## Guideline Category

Diagnosis

Technology Assessment
Clinical Specialty
Endocrinology
Family Practice
Geriatrics
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Radiology
Rheumatology
Intended Users
Physicians
Guideline Objective(s)
To outline the new 2013 International Society for Clinical Densitometry Official Positions regarding indications for body composition analysis using dual energy x-ray absorptiometry (DXA)
Target Population
Individuals at risk of very low lean body mass, very low fat mass, or very high fat mass (either regionally or systemically), including people living with human immunodeficiency virus (HIV), obesity, post-bariatric surgery or weight loss, and sarcopenia
Interventions and Practices Considered
Dual-energy x-ray absorptiometry (DXA) for total body composition measurement with regional analysis (indications and contraindications for use)
Major Outcomes Considered
<ul> <li>Accuracy and precision of body composition measurements using various modalities</li> <li>Sensitivity and reliability of dual-energy x-ray absorptiometry (DXA) for detecting changes in regional fat distribution</li> </ul>

Evaluation

Risk Assessment

Methodology

Methods Used to Collect/Select the Evidence

#### Description of Methods Used to Collect/Select the Evidence

Task Force members performed a medical literature search relevant to the clinical and/or technical questions using a method modified from that utilized by the Cochrane reviews. The literature searches were conducted using electronic databases from 1/1/1980 through 12/31/2012 and included PubMed, EMBASE and MEDLINE. Specific areas of focus were indications for body composition testing in persons living with HIV, patients after bariatric surgery, obese patients, anorexia, and sarcopenia. In addition, the Task Force searched the literature on other techniques for estimating body composition and contraindications to dual-energy X-ray absorptiometry (DXA) body composition testing. The references obtained were augmented by other pertinent references known by committee members but not appearing in the search strategy. The Appendix of the original guideline document lists the search terms used and the citations obtained.

#### Number of Source Documents

Not stated

#### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

#### Rating Scheme for the Strength of the Evidence

Quality of Evidence

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations.

Fair: Evidence is sufficient to determine effects on outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies.

Poor: Evidence is insufficient to assess the effects on outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Relevant publications from the literature search were downloaded and reviewed; the results collated in a data table. Presentations to the expert panel were formulated from this. The final positions agreed on by the expert panel were then brought into the document with the references supporting the final official positions.

The development of the International Society for Clinical Densitometry (ISCD) Official Positions was undertaken according to the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM). This is a mechanism to determine whether procedures or indications are expected to provide a specific health benefit, designated as "appropriate," that exceeds the potential negative consequences by such a wide margin that the procedure or indication is worth doing, exclusive of cost. The rationale for use of the RAM for the Position Development Conference (PDC) is based on its ability to combine the best available scientific evidence with the collective judgment of worldwide experts in the bone field, to yield appropriate recommendations that are patient- and technology-specific.

#### Methods Used to Formulate the Recommendations

Expert Consensus (Consensus Development Conference)

#### Description of Methods Used to Formulate the Recommendations

Position Development Conference (PDC) Expert Panel

Concurrent with Task Force work, international experts in the field of bone densitometry and societies specific to skeletal health were contacted by the PDC Steering Committee to serve as member panelists. Twelve experts agreed to participate on the PDC Expert Panel. In addition to individuals representing many regions of the world, one official representative from each of the following professional societies were participants on the expert panel: The American Society for Bone and Mineral Research (ASBMR), the North American Menopause Society (NAMS), and the National Osteoporosis Foundation (NOF). The role of the Expert Panel was to review the proposed Official Positions and supportive documents developed by the task forces and make final recommendations to the International Society for Clinical Densitometry Board of Directors (ISCD BOD).

#### **PDC** Moderators

PDC panel Moderators with experience in the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM) were selected by the Steering Committee. Two moderators assisted the Chair of the PDC in the development and refinement of statements derived from the initial Task Forces questions and sub-questions and, along with the Chair of the PDC, lead the discussion and the rating by the Expert Panel during the PDC in Tampa, Florida, USA.

#### Grading of the Official Positions

All Official Positions for the 2013 PDC were rated by the Expert Panel in the following categories: appropriateness, necessity, quality of evidence, strength of recommendations and application of recommendations (see the "Rating Scheme for the Strength of the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields).

Proposed ratings in all cases, except the RAM ratings for appropriateness and necessity for each of the above categories, were included in the preliminary Official Positions crafted by each Task Force. Final ratings were determined by the on site meeting, convened Expert Panel that included appropriateness and necessity.

A rating of "appropriate" was required in order for a statement to be sent to the BOD for selection as an ISCD Official Position. Ratings of each Official Position from the 2013 PDC are expressed in the form of four characters representing quality of the evidence, strength of the recommendation, application of the recommendation, and whether it is necessary as previously described. For example, a rating "Good-A-W-Necessary" indicates that the evidence includes consistent results from well-designed, well-conducted studies in representative populations, a strong recommendation supported by the evidence, worldwide recommendation, and is necessary to perform in all instances. Since PDC topics are often selected because strong medical evidence is unavailable, it is the nature of the process that Official Positions are not always supported by the highest possible level of evidence. Nevertheless, the ISCD Official Positions encourage consistent approaches in the clinical practice of bone densitometry, and focus attention on issues that require further study.

#### PDC Procedures

After the initial selection of topics by the Board of Directors and Scientific Advisory Committee, the PDC Steering Committee selected three Task Force chairpersons, one for each of the three major PDC topics. Thereafter, the PDC Steering Committee and Task Force chairpersons worked collectively to select international experts as members of their respective Task Forces with the knowledge required to evaluate their assigned PDC topic. All topic questions and sub-questions that were generated by each Task Force were thoroughly researched in the scientific medical literature.

Prior to the PDC meeting in Tampa, Florida, USA, topic questions and sub-questions were converted into recommendation statements that were sent to the Expert Panel for an initial "appropriateness" rating. The PDC required a median "appropriateness" rating in either the upper third or lower third of the rating continuum (continuum was 1 to 9 with clusters 7 to 9 representing the upper third and clusters 1 to 3 representing the lower third) without "disagreement." "Disagreement" was defined as lack of consensus being predetermined to be four or more Expert Panelists rating in extreme clusters 1 to 3 and 7 to 9. In circumstances where the median "appropriateness" rating was less than 7, no Official Position was developed.

In making its decisions, the Expert Panel considered the level of the medical evidence, expert opinion, and the clinical need for a recommendation.

In some instances, regulatory issues received consideration. The statements rated as "appropriate" with a median score of 7 or higher without "disagreement" by the Expert Panel were designated Official Positions. The statements rated as "uncertain" with a median score between four and six or any median score with "disagreement" were further discussed at the PDC. After the initial rating the documents supporting all Task Forces' recommendations were sent to the Expert Panelists for review. In brief, Task Force chairs presented reports on their topics supporting the "uncertain" statements to the Expert Panelists in closed session on the first day of the conference. These statements were then edited by Task Force chairs, if necessary, reflecting suggestions made by the Expert Panelists. Re-rating of "uncertain" statements occurred during each Task Force chairpersons' presentation when the PDC Moderators felt there was a significant likelihood of change in the opinions of the Expert Panel.

After all statements rated as "appropriate without disagreement" had been selected and all supporting evidence presented, the Expert Panel performed a final rating for necessity, quality of the evidence, strength of the recommendation, and application of the recommendation. The proposed Official Positions with supportive evidence were presented by the Task Force chairs at a meeting open to the public (in conjunction with the ISCD Annual Meeting) and attended by ISCD members, representatives from companies with interests in bone health and skeletal assessment, and other individuals with interest in bone disease and densitometry. All participants were encouraged to provide comments and suggestions to the expert panelists. On the next day, the Expert Panelists, in closed session, determined final wording of the proposed Official Positions.

### Rating Scheme for the Strength of the Recommendations

All Official Positions for the 2013 Position Development Conference were rated by the Expert Panel in the following categories:

Appropriateness: Statements that the Expert Panel rated as "appropriate without disagreement" according to predefined criteria derived from the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM) were referred to the International Society for Clinical Densitometry Board of Directors (ISCD BOD) with a recommendation to become ISCD Official Positions. A statement was defined as "appropriate" when the expected health benefit exceeded the expected negative consequences by a significant margin such that it was worth performing.

Necessity: Recommended Official Positions that were rated by the Expert Panel were then rated according to necessity to perform in all circumstances, i.e., whether the health benefits outweighed the risks to such an extent that it must be offered to all patients. Necessity rating was conducted in a similar fashion as the appropriateness rating, in that each Official Position had to be rated as necessary without disagreement using similar predefined RAM criteria.

Strength of Recommendations

A: Strong recommendation supported by the evidence

B: Recommendation supported by the evidence

C: Recommendation supported primarily by expert opinion

Application of Recommendations

W: Worldwide recommendation

L: Application of recommendation may vary according to local requirements

#### Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

The proposed Official Positions with supportive evidence were presented by the Task Force chairs at a meeting open to the public and attended by International Society for Clinical Densitometry (ISCD) members, representatives from companies with interests in bone health and skeletal assessment, and other individuals with interest in bone disease and densitometry. All participants were encouraged to provide comments and suggestions to the expert panelists. On the final day, the Expert Panelists, in closed session, determined final wording of the proposed Official Positions.

Following completion of the Position Development Conference, the Steering Committee finalized recommendation wording without changing content. These recommendations were then presented to the International Society for Clinical Densitometry Board of Directors (ISCD BOD) for review and voting. The BOD did not alter the content or wording of the proposed Official Positions. Recommendations approved by a majority vote of the ISCD BOD became ISCD Official Positions.

## Evidence Supporting the Recommendations

#### Type of Evidence Supporting the Recommendations

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

Since the field of bone densitometry is new and evolving, some clinically important issues that are addressed at the Position Development Conferences are not associated with robust medical evidence. Accordingly some Official Positions are based largely on expert opinion.

## Benefits/Harms of Implementing the Guideline Recommendations

#### Potential Benefits

- Identification of those with localized or systemic loss of lean body mass warranting intervention
- Identification of those with localized fat atrophy warranting intervention
- Specification, among those with a high body mass index, of the proportions of body mass that are lean tissue and adipose tissue

#### Potential Harms

- Low radiation exposure
- Contrast media and radiopharmaceuticals may be confounders for dual-energy x-ray absorptiometry (DXA) assessments with most
  instruments. They are, however, not true contraindications as once the contrast or isotope clears the body, there is no effect on DXA
  measurements. The length of time the artifact persists varies.

## Contraindications

#### Contraindications

- Pregnancy is a contraindication to dual-energy X-ray absorptiometry (DXA) body composition.
- The position to avoid scanning individuals exceeding the table weight limit is justified by the manufacturers' guidelines. These limits have been established for each device type based on the structural integrity and design of the instrument and, in some cases, also the ability to precisely and accurately measure patients at certain weights, likely because of inadequate penetration of the X-ray.

## **Qualifying Statements**

## **Qualifying Statements**

Since Position Development Conference topics are often selected because strong medical evidence is unavailable, it is the nature of the process that Official Positions are not always supported by the highest possible level of evidence. Nevertheless, the International Society for Clinical Densitometry (ISCD) Official Positions encourage consistent approaches in the clinical practice of bone densitometry, and focus attention on issues that require further study.

## Implementation of the Guideline

## Description of Implementation Strategy

An implementation strategy included publication of the International Society for Clinical Densitometry (ISCD) Official Positions in international journals that directly or indirectly pertain to skeletal diseases and the measurement of skeletal health.

Formal presentation of the ISCD Official Positions occurs at ISCD Annual Scientific Meetings, all ISCD Adult and Pediatric Bone Density Educational Courses, and ISCD Vertebral Fracture Assessment Educational courses. The Official Positions have been published in the society's official journal, *Journal of Clinical Densitometry and Assessment of Skeletal Health*.

#### Implementation Tools

Foreign Language Translations

Quick Reference Guides/Physician Guides

Staff Training/Competency Material

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

#### IOM Care Need

Living with Illness

Staying Healthy

#### **IOM Domain**

Effectiveness

## Identifying Information and Availability

## Bibliographic Source(s)

Kendler DL, Borges JL, Fielding RA, Itabashi A, Krueger D, Mulligan K, Camargos BM, Sabowitz B, Wu CH, Yu EW, Shepherd J. The official positions of the International Society for Clinical Densitometry: indications of use and reporting of DXA for body composition. J Clin Densitom 2013 Oct-Dec;16(4):496-507. [137 references] PubMed

## Adaptation Not applicable: The guideline was not adapted from another source. Date Released 2013 Oct-Dec Guideline Developer(s) International Society for Clinical Densitometry - Nonprofit Organization Source(s) of Funding International Society for Clinical Densitometry Guideline Committee Indications for Body Composition Analysis Studies Using DXA Task Force Composition of Group That Authored the Guideline Task Force Members: David L. Kendler, MD (Chair), University of British Columbia, Vancouver, Canada; Joao L. C. Borges, MD, Universidade Catolica de Brasilia, Brasilia, Brazil; Roger A. Fielding, PhD, Nutrition, Exercise Physiology, and Sarcopenia Laboratory, Jean Mayer USDA Human Nutrition Research Center on Aging at Tuffs University, Boston, MA, USA; Akira Itabashi, MD, PhD, Tokyo, Japan; Diane Krueger, BS, CBDT, University of Wisconsin, Madison, WI, USA; Kathleen Mulligan, PhD, University of California San Francisco, San Francisco, CA, USA; Bruno M. Carrargos, MD, CCD, Hospital Mater Dei, Belo Horizonte, Brazil; Brian Sabowitz, MD, FACP, CCD, Sacramento, CA, USA; Chih-Hsing Wu, MD, Department of Family Medicine, National Cheng Kung University Hospital, Tainan, Taiwan; Elaine W. Yu, CCD, Harvard Medical School, Massachusetts General Hospital, Boston, MA, USA; John Shepherd, PhD, CCD, University of California San Francisco, San Francisco, CA, USA Financial Disclosures/Conflicts of Interest None disclosed Guideline Status This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available to subscribers from the Journal of Clinical Densitometry Web site

Print copies: Available from the International Society for Clinical Densitometry, 101 Centerpoint Drive, Suite 208, Middletown, CT 06457; Phone: (860) 259-1000; Fax: (860) 259-1030; Web site: www.iscd.org

## Availability of Companion Documents

The following are available:

•	2013 official positions of the International Society for Clinical Densitometry. 2013 Aug 15.	16 p. Electronic copies: Available from the
	International Society for Clinical Densitometry (ISCD) Web site	Chinese and Indonesian translations of the
	official positions are also available from the ISCD Web site	
•	Body composition analysis course. Available from the ISCD Web site	

#### Patient Resources

None available

#### **NGC Status**

This NGC summary was completed by ECRI Institute on August 21, 2014. The information was verified by the guideline developer on September 30, 2014.

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